Attorney Docket No. 5618P2971

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of:	
Timothy R. Owens, et al.	Examiner: Roy, Baisakhi
Application No. 10/008,456	Art Unit: 3737
Filed: November 2, 2001	Confirmation No.: 5019
For: **A METHOD AND APPARATUS FOR COMPUTER MODIFIED MAGNETIC RESONANCE IMAGING**	

APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37(c) for consideration by the Board of Patent Appeals and Interferences. Applicant also submits herewith a check in the amount of $510 to cover the cost of filing the opening brief as required by 37 C.F.R. §1.17(f). Please charge any additional amount due or credit any overpayment to Deposit Account No. 02-2666.

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I. REAL PARTY IN INTEREST

Timothy R. Owens, James M. Cannon, Jr. and Gregory Matthew Hyde transferred their rights to the subject Application through an assignment recorded on May 24, 2002 (Reel/Frame 012674/0514) in the patent application to Advanced Cardiovascular Systems, Inc., of Santa Clara, California. Thus, as the owner at the time the brief is being filed, Advanced Cardiovascular Systems, Inc. is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences that will affect or be affected by the outcome of this appeal.

III. STATUS OF CLAIMS

Claims 1-49 are pending and rejected in the Application. Applicant hereby appeals the rejection of all pending claims.

IV. STATUS OF AMENDMENTS

The claims are amended in accordance with an Amendment and Response to Office Action filed June 6, 2007. The claim amendments presented at that time were entered. Accordingly, the claims stand as amended June 6, 2007.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

In one embodiment, an apparatus is disclosed that includes a medical device adapted to be inserted into an anatomy with a plurality of target markers disposed on a proximal portion of the medical device. See, e.g., paragraph [0015]. In one embodiment recited in claim 2, the plurality of target markers disposed on the medical device are ferromagnetic or paramagnetic materials. See, e.g., paragraphs [0051], [0055], [0057] and [0058]. Geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy. See, e.g., paragraph [0017]. The system may also include a control unit and a display connected to a processor. The system is configured such that it is unable to detect or will disregard MRI signals of the target markers within an anatomy

of, for example, a human without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system. See, e.g., paragraph [0016]. Examples of a suitable medical device include those set forth in claim 4 of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter. See, e.g., paragraphs [0054], [0056]. The medical device may comprise a polymer material (claim 5). See, paragraphs [0046], [0055]. The medical device may also be expandable (claim 6). See, e.g., paragraphs [0047], [0056], [0059] and [0060]. An example of a medical device and system are illustrated schematically in Figure 3.

Typical MRI systems are programmed to discard signals at a threshold sensitivity level. Typical MRI systems operate at a magnetic flux density in the range of 0.2-5.0 Tesla. See, e.g., paragraph [0051] (claim 3). Most threshold sensitivity levels are too high to detect a signal generated from a small amount of ferromagnetic or paramagnetic material on a medical device inserted into an anatomy. In some systems, the background signals are at such a level as to render low-level ferromagnetic or paramagnetic material on a medical device inserted onto an anatomy undetectable. Therefore, with a background signal having a higher signal-to-noise ratio (SNR), the low-level signal produced from a low level of ferromagnetic or paramagnetic material on a medical device inserted in an anatomy is discarded as noise without low-level signal detection processing.

The Application describes a technique for imaging a medical device having otherwise non-detectable or typically disregardable markers for an MRI system with reference to Figures 4A-4E. In this example, a catheter body having ferromagnetic and paramagnetic target markers is scanned by pre-scanner 360 outside of an anatomy. After scanning device 350, pre-scanner 360 transmits data to a low level detection processor 320. The data transmitted to low-level detection processor 320 includes geometrical information about device 350, such as length, width, height, etc. Along with the geometrical information transmitted to low-level detection processor 320, coordinates of target markers (in relation to the geometric information of device 350) are also transmitted to processor 320. See, e.g., paragraph [0064].

With the geometric information and coordinates of target markers, low-level detection processor 320 is capable of determining a geometric orientation of device 350 within an anatomy based on the orientation of detected target markers 420 within an anatomy, in relation to the known geometric and target information. See, e.g., paragraph [0068]. In one embodiment, pre-

scanner 360 scans device 350 outside an anatomy and stores a multi-dimensional (e.g., two-dimensional or three-dimensional) image of device 350 in memory image processor 310. When device 350 is placed in anatomy 340, scanner 330 may detect low-level target markers 410 from low-level detection processor 320. Image processor 310 can process the anatomy and device in anatomy 340 simultaneously. Processor 320 can then determine the geometrical orientation of device 350 in the anatomy and create a visual image of the anatomy without the inserted device 350 (claim 7). See, e.g., paragraph [0069].

In one embodiment, processor 320 superimposes the stored multi-dimensional image of previously scanned device 350 onto the exact determined anatomy that the image processor detected the device location in anatomy 340. In this embodiment, an accurate and informative visual version of device 350 in anatomy can be displayed on display 380. See, e.g., paragraph [0070]. Therefore, processor 320, unlike typical MRI systems that disregard the low-level signals as noise, uses the detected low-level signals to position (e.g., superimpose) a scanned image of device 350 according to its orientation in anatomy. By using a scanned image of device 350, device 350 may accurately display as it is positioned in the anatomy. See, e.g., paragraph [0070].

Claims 8-22 relate to a system. The system includes a MRI processor including MRI low-level signal detection process stored in a memory; a MRI scanner coupled to the processor; a control unit coupled to the processor; a display coupled to the processor; and a medical device adapted to insert into an anatomy. The medical device has a plurality of target markers, wherein geometric information for the target markers is stored in the memory prior to insertion of the medical device into the anatomy. The MRI signals of the plurality of target markers within the anatomy are not detectable or disregardable as noise for MRI systems (a) without a MRI low-level signal detection process and (b) without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold. See, e.g., paragraphs [0064]-[0070].

As described in claims 9-10, the system may include a pre-scanning device coupled to the processor that may transmits geometric data, a plurality of image data, or a plurality of geometric data and image data of a medical device and a plurality of target markers to the processor. See, e.g., paragraph [0064].

As provided in claim 11, the plurality of target markers may include one of ferromagnetic and paramagnetic material. See, e.g., paragraphs [0051], [0055], [0057] and [0058]. As provided in claim 12, the plurality of target markers are disregarded by an MRI system operating between 0.2 and 5.0 Tesla. See, e.g., paragraph [0051].

As provided in claim 13, the medical device may be a fluid delivering catheter, a stent delivering device, a photographic device or a balloon catheter. See, e.g., paragraphs [0054] and [0056]. In claim 14, the medical device comprises a polymer material. See, e.g., paragraphs [0046] and [0057]. The medical device may also be expandable as provided in claim 15. See, e.g., paragraphs [0047], [0056] and [0059]-[0060].

Claim 16 describes a system wherein an orientation and a location of the medical device in relation to the anatomy is determinable based on the location of the plurality of target markers. See, e.g., paragraph [0069]. Claim 17 provides that the image of the medical device is superimposed on an image of the anatomy, the superimposed image having the same orientation and location that the medical device has within the anatomy. See, e.g., paragraphs [0069]-[0070]. Claim 18 describes that a plurality of pixels of the medical device replace a plurality of pixels of an image of an anatomy at a same location that the medical device is located within the anatomy, the plurality of pixels of the medical device having the same orientation that the medical device has within the anatomy. See, e.g., paragraph [0070].

Claim 19 describes the system of claim 8 wherein the memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of the medical device. See, e.g., paragraph [0069].

Claim 20 provides that the MRI low-level signal detection process adjusts a signal detection threshold to detect a low-level MRI signal produced from the target markers. See, e.g., paragraph [0052]. Claim 21 provides a system wherein a non-adjusted signal threshold will one of disregard or fail to detect the low-level MRI signal produced from the target markers. See, e.g., paragraph [0052]. Claim 22 provides that the MRI low-level signal detection process determines to recognize low-level MRI signals returned from the target markers upon a match from a comparison of known geometric data from the target markers with the returned low-level MRI signals. See, e.g., paragraph [0069].

Claims 23-33 relate to a method. The method includes inserting a medical device into an anatomy, the medical device having a plurality of target markers; storing geometric information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy; scanning an MRI of the anatomy; processing the scanned image by a MRI processor coupled to the memory; determining a location and orientation of the medical device inserted in the anatomy in relation to the anatomy based on the plurality of the target markers; and displaying a precise image of the medical device within the anatomy. The MRI signals of the plurality of target markers within the anatomy are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold. See, e.g., paragraphs [0064]-[0070].

Claim 24 includes pre-scanning the medical device before inserting the medical device into an anatomy; and transmitting one of a plurality of geometric data, a plurality of image data, or a plurality of geometric data and a plurality of image data of the medical device and the plurality of target markers to the MRI processor. See, e.g., paragraph [0069].

Claim 25 provides that the plurality of target markers comprise one of ferromagnetic and paramagnetic material. See, e.g., paragraphs [0051], [0055]. [0057] and [0058]. Claim 26 provides that the MRI signals of the plurality of target markers are one of not detectable and disregarded by MRI systems operating between 0.2 and 5.0 Tesla. See, e.g., paragraph [0051].

Claim 27 provides that the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter. See, e.g., paragraphs [0054] and [0056].

Claim 28 provides that the medical device comprises a polymer material. See, e.g., paragraphs [0046] and [0055]. Claim 29 provides that the medical device is expandable. See, e.g., paragraphs [0047], [0056], [0059] and [0060].

Claim 30 provides that the method includes superimposing a stored image of the medical device over an image of the anatomy, the superimposed image having the same orientation and location that the medical device has within the anatomy. See, e.g., paragraph [0070].

Claim 31 provides that the method further includes replacing a plurality of pixels of an

image of an anatomy with a plurality of pixels of the medical device at the same location that the medical device is located within the anatomy, the plurality of pixels of the medical device having the same orientation that the medical device has within the anatomy. See, e.g., paragraph [0070].

Claim 32 provides that a memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device and the plurality of target markers. See, e.g., paragraph [0061]. Claim 33 provides that processing the scanned image further includes adjusting the signal detection threshold to detect low-level MRI signals produced from the plurality of target markers, wherein if the signal detection threshold is unadjusted the low-level MRI signals produced from the plurality of target markers will be disregarded. See, e.g., paragraph [0052].

Claims 34-44 describe an apparatus comprising a machine-readable medium containing instructions which, when executed by a machine, cause the machine to perform operations comprising storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted into the anatomy; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on the geometric information of the plurality of target markers; and displaying a precise image of the medical device within the anatomy. The MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold. See, e.g., paragraphs [0064]-[0070] and [0079]-[0080].

Claim 35 describes instructions which cause the machine to perform operation including pre-scanning the medical device before the medical device is inserted in an anatomy; transmitting one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device and the plurality of target markers to the MRI processor; and withdrawing a medical device from an anatomy at a dynamically adjusted pace. See, e.g., paragraphs [0064]-[0070] and [0079]-[0080].

Claim 36 describes the plurality of target markers comprise one of ferromagnetic and

paramagnetic material. See, e.g., paragraphs [0051], [0055], [0057]-[0058]. Claim 37 provides that the MRI signals of the plurality of target markers are one of not detectable and disregarded by MRI systems operating between 0.2 and 5.0 Tesla. See, e.g., paragraph [0051]. Claim 38 provides that the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter. See, e.g., paragraphs [0054] and [0056]. Claim 39 provides that the medical device comprises a polymer material. See, e.g., paragraphs [0046] and [0055]. Claim 40 provides that the medical device is expandable. See, e.g., paragraphs [0047], [0056] and [0059]-[0060].

Claim 41 provides instructions which, when executed, cause a machine to perform operations including superimposing an image of the medical device over an image of the anatomy, the superimposed image having the same location and orientation that the medical device has within the anatomy. See, e.g., paragraph [0070]. Claim 42 provides replacing a plurality of pixels of an image of an anatomy with a plurality of pixels of the medical device, the plurality of pixels of the medical device having the same location and orientation that the medical device has within the anatomy. See, e.g., paragraph [0070].

Claim 43 provides that the memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device. See, e.g., paragraph [0069]. Claim 44 provides that the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the target markers. See, e.g., paragraph [0052].

Claims 45-46 describe an apparatus comprising a machine-readable medium containing instructions which, when executed by a machine, cause the machine to perform operations comprising: storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a MRI of the anatomy with the medical device inserted; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on detection of the plurality of target markers in relation to the medical device and each of the plurality of target markers, wherein geometric data of the medical device and the plurality of target markers is stored before the medical device is inserted into the anatomy; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of

target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the geometric information of the plurality of target markers to lower an MRI signal detection threshold. See, e.g., paragraphs [0064]-[0070] and [0079]-[0080]. Claim 46 provides that the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the plurality of target markers. See, e.g., paragraph [0052].

Claims 47-49 describe a system comprising: a MRI processor including an MRI low-level signal detection process stored in a memory; a MRI scanner coupled to the processor; a control unit coupled to the processor; a display coupled to the processor; and a medical device to insert into an anatomy. The medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy. MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the stored geometric information of the plurality of target markers to lower an MRI signal detection threshold. The geometric information includes geometric information of the medical device and each of the plurality of target markers to determine location and orientation of the medical device in relation to the anatomy. See, e.g., paragraphs [0064]-[0070].

Claim 48 provides that the low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the target markers. See, e.g., paragraph [0052]. Claim 49 provides that the geometric information of the medical device and a position of the detected plurality of target markers are used to display an image of the medical device superimposed on an image of an anatomy, the combined images representative of the actual location and orientation of the medical device in the anatomy. See, e.g., paragraph [0070].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection in this appeal are:

A. Whether claims 1, 4-10, 13-24, 27-35 and 38-49 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,272,370 of Gillies et al. (Gillies) in view of U.S. Patent No. 6,167,292 of Badano et al. (Badano); and

B. Whether claims 2-3, 11-12, 25-26 and 36-37 are obvious over Gillies in view of Badano and further in view of U.S. Patent No. 5,817,017 of Young et al. (Young).

VII. ARGUMENT

A. Summary of Cited References

1. U.S. Patent No. 6,272,370

U.S. Patent No. 6,272,370 of Gillies et al. (Gillies) discloses a device and method for targeted drug delivery, especially intracranial infusion or retroperfusion using nonlinear magnetic stereotaxis in combination with MRI and/or x-ray visualization. See Abstract. Gillies uses MRI in combination with 1) an MR observable delivery device, or 2) an MR observable medical device which can alter a water-based molecular environment by performed medical operations, the delivery device and medical device in the presence of MR observable (in water, body fluid or tissue) compound(s) or composition(s). Col. 6, lines 27-33.

> The invention includes a device for use in conjunction with magnetic stereotaxis guidance and device delivery and a method of MR-guided targeted drug delivery into a patient, such as intracranial drug delivery, intraspinal drug delivery, intrarenal drug delivery, intracardial drug delivery, etc. The MR-visible drug delivery device is guided by magnetic stereotaxis to the target tissue and/or advanced within entrance point to the patient . . . under magnetic resonance imaging or real time X-ray fluoroscopy, and all of these is possibly also done with conjunction with conventional methods of neurosurgical or neuroradiologic catheter manipulation. The drug delivery device preferably has a linearly arranged array of radiopaque and MR-visible markers disposed at its distal end to provide easily identifiable reference point for trackability and localization under susceptibility MRI imaging and X-ray fluoroscopy guidance. Additionally, active MR visualization of the drug delivery device is achieved to enhance by

> means of RF microcoils positioned along the distal axis of the device. MR visibility can be variably adjusted based on requirements related to degree of signal intensity change for device localization and positioning, enhancement along the shaft of the device, enhancement around the body of the device, visibility of the proximal and distal end to the device, degree of increased background noise associated with the device movement, and other factors with which either increased or suppressed background noise is associated with the device. Since the tip of the drug delivery device can be seen on MR and X-ray images and thus localized within the brain, the multiple point source location of drug delivery are therefore known and can be seen relative to the tip or shaft of the device.

Col. 8, lines 3-35.

In an embodiment related to targeted intracranial drug delivery, an MR-visible drug delivery device is guided into the distal cerebrovasculature using a combination of flow-directed, manual manipulation, and magnetic stereotaxis steering without reducing cerebro perfusion in the affected vascular territory. See col. 10, lines 51-61. Magnetic stereotaxis involves first fitting a patient with fiducial markers that are fixed to the skull and which are visible in both MR and X-ray images. After these markers are placed in an appropriate array on the skull, the patient is given a pre-operative MR brain scan, the results of which constitute an atlas of the images that define the location of critical brain structure and any potential target locations (e.g., a specific part of a tumor) relative to the fixed fiducial markers. The atlas of images is then stored in the host computer system used by the clinician to control the magnetic stereotaxis system. See col. 11, lines 3-13.

Following a procedure such as stereotaxis, Gillies describes an operation involving an initial MR imaging observation of a molecular environment of a patient or a target at a given time and/or state. Then, the distribution of a delivered material in the tissue is determined (by MR real time imaging) by releasing an amount of material through a drug delivery device (which was already positioned in the tissue by magnetic stereotaxis and location-confirm) while being observed with MRI. The material is allowed to diffused or perfused into the tissue and the resulting MR signal intensity is analyzed. On a continual basis or at some subsequent time interval, the MR image of the molecular state within the same general area is observed. See col. 14, lines 1-41.

Gillies does not teach or disclose that geometric information for a plurality of target markers is stored in an MRI system prior to insertion of a medical device into an anatomy. Gillies further does not disclose an MRI system that unable to detect or will disregard MRI signal of target markers within an anatomy as noise without using stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system. Gillies does not mention the lowering of an MRI signal detection threshold.

2. U.S. Patent No. 6,167,292

U.S. Patent No. 6,167,292 of Badano et al. (Badano) discloses a device for use in robotic surgery. In one aspect, Badano provides a method of bringing to register for preferably robotic image-guided surgery a procedure step of taking a preprocedure image of the anatomic structure where the surgical operation is to be performed. It does this by providing an anatomic structure with marker elements for marking the anatomic structure and making them visible on an image. See col. 6, lines 6-14. In other words, Badano teaches marking a body part with markers that are visible in taking an image. Badano does not teach, disclose or suggest insertion of a medical device into an anatomy where the medical device includes markers and geometric information on the markers is stored before insertion. Instead, any markers are attached externally to a patient (e.g., attached to a person's skull from outside the person's body).

3. U.S. Patent No. 5,817,017

U.S. Patent No. 5,817,017 of Young et al. (Young) discloses catheters and other medical devices including a non-metallic member having a paramagnetic ionic particles fixedly incorporated therethrough in order to provide enhanced detectability when viewed by MRI regardless of the orientation of the non-metallic member in the magnetic field. See Abstract. Specifically, paramagnetic iron is a small iron and/or superparamagnetic particles are described.

B. 35 U.S.C. §103(a): Rejection of Claims 1, 4-10, 13-24, 27-35 & 38-49

The Patent Office rejects claims 1, 4-10, 13-24, 27-35, 38-49 are rejected in the Office Action under 35 U.S.C. §103(a), as obvious over Gillies, in view of Badano.

According to MPEP §2142, the Patent Office bears the initial burden of factually supporting any prima facie conclusion of obviousness. To reach a proper determination under 35

U.S.C. §103, the Patent Office must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was known and just before it was made. In view of the factual information, the Patent Office must then make a determination whether the claimed invention as a whole would have been obvious at that time to that person. Knowledge of Applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct a search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to hindsight based upon Applicant's disclosure is impermissible and must be avoided.

Gillies discloses a device and method for targeted drug delivery. An embodiment of the device disclosed in Gillies is "MR-visible." See col. 10, lines 56-61. The device includes a magnetic tip. In another embodiment, Gillies discloses an MR-visible microdialysis probe. See col. 13, lines 37-42. Gillies further uses coils and an amplifier circuit for RF signals. Gillies, however, does not teach, disclose or suggest that geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system. Further, in Gillies, there is no mention of lowering of an MRI signal detection threshold.

Badano discloses a preprocedure step of taking a preprocedure image of an anatomic structure (i.e., a body part of a person) where the surgical operation is to be performed using marker elements for marking the anatomical structure. See Badano, col. 6, lines 8-14. In other words, Badano teaches marking a body part with markers that are visible when taking an image. Badano does not teach, disclose or suggest insertion of a medical device into an anatomy where the medical device includes markers and geometric information on the markers is stored before insertion. The device of Badano is first fixed to a person (e.g., attached to a person's skull from outside the person's body). This anchor receives a support element that includes markers, which are never inserted into an anatomy as the markers are fixed to first and second support elements, which would cause death if inserted into a person's anatomy.

Moreover, the invention disclosed by Badano is completely different and incompatible from that disclosed Gillies. That is, teachings from Gillies and Badano cannot be combined (i.e.,

Badano uses images made from the help of a device outside an anatomy while Gillies needs to view imaging with help from a device placed inside an anatomy).

Therefore, neither Gillies, Badano, and any resulting invention from the combination of the two teach, disclose, suggest or provide any prediction for:

Applicant's claim 1 limitations of

> a medical device adapted to be inserted into an anatomy; and a plurality of target markers disposed on a proximal portion of the medical device, wherein geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system,

Applicant's claim 8 limitations of

> a medical device adapted to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are not detectable or disregardable as noise for MRI systems (a) without the MRI low-level signal detection process and (b) without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold,

Applicant's claim 23 limitations of

> storing geometric information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy; scanning a magnetic resonance image (MRI) of the anatomy; processing the scanned image by a MRI processor coupled to the memory; determining a location and orientation of the medical device inserted in the anatomy in relation to the anatomy based on the plurality of target markers; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold,

Applicant's claim 34 limitations of

> storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted into the anatomy; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on the geometric information of the plurality of target markers; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold,

Applicant's claim 45 limitations of

> storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on detection of the plurality of target markers in relation to the medical device and each of the plurality of target markers, wherein geometric data of the medical device and the plurality of target markers is stored before the medical device is inserted into the anatomy; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the geometric information of the plurality of target markers to lower an MRI signal detection threshold,

nor Applicant's claim 47 limitations of

> a medical device to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the stored geometric information of the plurality of

target markers to lower an MRI signal detection threshold, and wherein the geometric information includes geometric information of the medical device and each of the plurality of target markers to determine location and orientation of the medical device in relation to the anatomy.

Since neither Gillies, Badano, nor the combination of the two, teach, disclose, suggest or provide any prediction for all the limitations of Applicant's amended claims 1, 8, 23, 34, 45 and 47, as listed above, Applicant's amended claims 1, 8, 23, 34, 45 and 47 are not obvious over Gillies in view of Badano since a *prima facie* case of obviousness has not been met under MPEP §2142. Additionally, the claims that directly or indirectly depend from amended claims 1, 8, 23, 34, 45 and 47, namely claims 4-7, 9-20 and 13-22, 24 and 27-33, 35 and 38-44, and 48-49, respectively, would also not be obvious over Gillies in view of Badano for at least the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections for Claims 1, 4-10, 13-24, 27-35, 38-49 are respectfully requested.

C. 35 U.S.C. §103(a): Rejection of Claims 2-3, 11-12, 25-26, 36 & 37

The Patent Office rejects claims 2, 3, 11, 12, 25, 26, 36 and 37 under 35 U.S.C. §103(a), as obvious over Gillies in view of Badano, and further in view of Young. Applicant respectfully traverses the aforementioned rejection for the following reasons.

Applicant's claims 2-3 either directly or indirectly depend from Amended claim 1. Applicant's claims 11-12 either directly or indirectly depend from Amended claim 8. Applicant's claims 25-26 either directly or indirectly depend from Amended claim 23. Applicant's claims 36-37 either directly or indirectly depend from Amended claim 34. Applicant has addressed amended claims 1, 8, 23 and 34 regarding Gillies in view of Badano above in section I(A).

Young is relied on for disclosing paramagnetic markers and a typical MRI system operating at 1.5 Tesla. Young, however, does not teach, disclose, suggest or predict that markers on a medical device inserted in an anatomy are undetectable or discarded as noise in a typical MRI operating range unless an MRI low-level signal detection process is used based on previously stored information.

That is, even if Gillies, Badano and Young are combined in any way, the resulting invention would still not teach, disclose or suggest Applicant's independent claims 1, 8, 23 and 34 limitations, as listed above.

Since neither Gillies, Badano, Young, and therefore, nor the combination of the three, teach, disclose, suggest or provide any prediction for all the limitations of Applicant's amended claims 1, 8, 23 and 34, as listed above, Applicant's amended claims 1, 8, 23 and 34 are not obvious over Gillies in view of Badano and Young since a *prima facie* case of obviousness has not been met under MPEP §2142. Additionally, the claims that directly or indirectly depend from amended claims 1, 8, 23 and 34, namely claims 2-3, 11-12, 25-26, and 36-37, respectively, would also not be obvious over Gillies in view of Badano and Young for the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections for Claims 2, 3, 11, 12, 25, 26, 36 and 37 are respectfully requested.

In view of the foregoing, it is believed that all claims now pending (1) are in proper form, (2) are not obvious over the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Patent Office believes that a telephone conference would be useful moving the application forward to allowance, the Patent Office is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

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Dated: 4/28/08

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 4/28/08

Nedy Calderon Date

VIII. CLAIMS APPENDIX

The claims involved in this Appeal are as follows:

1. (Previously Presented) An apparatus comprising:

a medical device adapted to be inserted into an anatomy; and

a plurality of target markers disposed on a proximal portion of the medical device,

wherein geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system.

2. (Original) The apparatus of claim 1, wherein the plurality of target markers comprise one of ferromagnetic and paramagnetic material.

3. (Previously Presented) The apparatus of claim 2, wherein MRI signals of the plurality of target markers are disregarded by MRI systems as noise operating between 0.2 and 5.0 Tesla.

4. (Previously Presented) The apparatus of claim 1, wherein the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter.

5. (Original) The apparatus of claim 4, wherein the medical device comprises a polymer material.

6. (Original) The apparatus of claim 4, wherein the medical device is expandable.

7. (Previously Presented) The apparatus of claim 1, wherein the orientation and location of the medical device in relation to the anatomy is determinable based on the location of the plurality of target markers in relation to the medical device.

8. (Previously Presented) A system comprising:

a magnetic resonance imaging (MRI) processor, the processor including an MRI low-level signal detection process stored in a memory;

a MRI scanner coupled to the processor;

a control unit coupled to the processor;

a display coupled to the processor; and

a medical device adapted to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are not detectable or disregardable as noise for MRI systems (a) without the MRI low-level signal detection process and (b) without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

9. (Original) The system of claim 8, further comprising a pre-scanning device coupled to the processor.

10. (Original) The system of claim 9, wherein the pre-scanner transmits one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device and the plurality of target markers to the processor.

11. (Original) The system of claim 8, wherein the plurality of target markers comprise one of ferromagnetic and paramagnetic material.

12. (Previously Presented) The system of claim 11, wherein MRI signals of the plurality of target markers are disregarded by MRI systems operating between 0.2 and 5.0 Tesla.

13. (Original) The system of claim 8, the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter.

14. (Original) The system of claim 13, wherein the medical device comprises a polymer material.

15. (Original) The system of claim 14, wherein the medical device is expandable.

16. (Previously Presented) The system of claim 8, wherein an orientation and a location of the medical device in relation to the anatomy is determinable based on the location of the plurality of target markers.

17. (Previously Presented) The system of claim 8, wherein an image of the medical device is superimposed on an image of the anatomy, the superimposed image having the same orientation and location that the medical device has within the anatomy.

18. (Previously Presented) The system of claim 8, wherein a plurality of pixels of the medical device replace a plurality of pixels of an image of an anatomy at a same location that the medical device is located within the anatomy, the plurality of pixels of the medical device having the same orientation that the medical device has within the anatomy.

19. (Previously Presented) The system of claim 8, wherein the memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of the medical device.

20. (Previously Presented) The system of claim 8, wherein the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the target markers.

21. (Previously Presented) The system of claim 20, wherein a non-adjusted signal threshold will one of disregard or fail to detect the low-level MRI signal produced from the target markers.

22. (Previously Presented) The system of claim 8, wherein the MRI low-level signal detection process determines to recognize low-level MRI signals returned from the target markers upon a match from a comparison of known geometric data from the target markers with the returned low-level MRI signals.

23. (Previously Presented) A method comprising:

inserting a medical device into an anatomy, the medical device having a plurality of target markers;

storing geometric information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy;

scanning a magnetic resonance image (MRI) of the anatomy;

processing the scanned image by a MRI processor coupled to the memory;

determining a location and orientation of the medical device inserted in the anatomy in relation to the anatomy based on the plurality of target markers; and

displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

24. (Previously Presented) The method of claim 23, further comprising:

pre-scanning the medical device before inserting the medical device into an anatomy; and

transmitting one of a plurality of geometric data, a plurality of image data, or a plurality of geometric data and a plurality of image data of the medical device and the plurality of target markers to the MRI processor.

25. (Original) The method of claim 23, wherein the plurality of target markers comprise one of ferromagnetic and paramagnetic material.

26. (Previously Presented) The method of claim 25, wherein MRI signals of the plurality of target markers are one of not detectable and disregarded by MRI systems operating between 0.2 and 5.0 Tesla.

27. (Original) The method of claim 23, wherein the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter.

28. (Original) The method of claim 27, wherein the medical device comprises a polymer material.

29. (Original) The method of claim 27, wherein the medical device is expandable.

30. (Previously Presented) The method of claim 23, further including superimposing a stored image of the medical device over an image of the anatomy, , the superimposed image having the same orientation and location that the medical device has within the anatomy.

31. (Previously Presented) The method of claim 23, further including replacing a plurality of pixels of an image of an anatomy with a plurality of pixels of the medical device at the same location that the medical device is located within the anatomy, the plurality of pixels of the medical device having the same orientation that the medical device has within the anatomy.

32. (Previously Presented) The method of claim 23, wherein the memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device and the plurality of target markers.

33. (Previously Presented) The method of claim 23, wherein processing the scanned image further includes:

adjusting the signal detection threshold to detect low-level MRI signals produced from the plurality of target markers, wherein if the signal detection threshold is unadjusted the low-level MRI signals produced from the plurality of target markers will be disregarded.

34. (Previously Presented) An apparatus comprising a machine-readable medium containing instructions which, when executed by a machine, cause the machine to perform operations comprising:

storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy;

scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted into the anatomy;

processing the scanned image by a MRI processor coupled to the memory, the MRI

processor having an MRI low-level signal detection process;

determining a location and orientation of the medical device in relation to the anatomy based on the geometric information of the plurality of target markers; and

displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

35. (Original) The apparatus of claim 34, further containing instructions which, when executed by the machine, cause the machine to perform operations including:

pre-scanning the medical device before the medical device is inserted in an anatomy;

transmitting one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device and the plurality of target markers to the MRI processor; and

withdrawing a medical device from an anatomy at a dynamically adjusted pace.

36. (Original) The apparatus of claim 34, wherein the plurality of target markers comprise one of ferromagnetic and paramagnetic material.

37. (Previously Presented) The apparatus of claim 36, wherein the MRI signals of the plurality of target markers are one of not detectable and disregarded by MRI systems operating between 0.2 and 5.0 Tesla.

38. (Original) The apparatus of claim 34, wherein the medical device is one of a fluid delivering catheter, a stent delivering device, a photographic device and a balloon catheter.

39. (Original) The apparatus of claim 38, wherein the medical device comprises a polymer material.

40. (Original) The apparatus of claim 38, wherein the medical device is expandable.

41. (Previously Presented) The apparatus of claim 34, further containing instructions which, when executed by the machine, cause the machine to perform operations including:

superimposing an image of the medical device over an image of the anatomy, the superimposed image has the same location and orientation that the medical device has within the anatomy.

42. (Previously Presented) The apparatus of claim 34, further containing instructions which, when executed by the machine, cause the machine to perform operations including:

replacing a plurality of pixels of an image of an anatomy with a plurality of pixels of the medical device, the plurality of pixels of the medical device having the same location and orientation that the medical device has within the anatomy.

43. (Previously Presented) The apparatus of claim 34, wherein the memory stores one of a plurality of geometric data, a plurality of image data, and a plurality of geometric data and a plurality of image data of a medical device.

44. (Previously Presented) The apparatus of claim 34, wherein the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the target markers.

45. (Previously Presented) An apparatus comprising a machine-readable medium containing instructions which, when executed by a machine, cause the machine to perform operations comprising:

storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy;

scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted;

processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process;

determining a location and orientation of the medical device in relation to the anatomy based on detection of the plurality of target markers in relation to the medical device and each of the plurality of target markers, wherein geometric data of the medical device and the plurality of

target markers is stored before the medical device is inserted into the anatomy; and

displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the geometric information of the plurality of target markers to lower an MRI signal detection threshold.

46. (Previously Presented) The apparatus of claim 45, wherein the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the plurality of target markers.

47. (Previously Presented) A system comprising:

a magnetic resonance imaging (MRI) processor, the processor including an MRI low-level signal detection process stored in a memory;

a MRI scanner coupled to the processor;

a control unit coupled to the processor;

a display coupled to the processor; and

a medical device to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the stored geometric information of the plurality of target markers to lower an MRI signal detection threshold, and wherein the geometric information includes geometric information of the medical device and each of the plurality of target markers to determine location and orientation of the medical device in relation to the anatomy.

48. (Previously Presented) The system of claim 47, wherein the MRI low-level signal detection process adjusts the signal detection threshold to detect a low-level MRI signal produced from the target markers.

49. (Previously Presented) The system of claim 48, wherein the geometric information of the medical device and a position of the detected plurality of target markers are used to display an image of the medical device superimposed on an image of an anatomy, the combined images representative of the actual location and orientation of the medical device in the anatomy.

IX. EVIDENCE APPENDIX

No evidence is submitted with this appeal.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings exist.